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(71) Applicant : **ARTHREX MEDIZINISCHE
INSTRUMENTE GmbH**
Liebigstrasse 13
D-85757 Karlsfeld (DE)

(72) Inventor : **Schmieding, Reinhold**
163 Eugena Drive
Naples, FL 33942 (US)

(74) Representative : **Köster, Hajo, Dr.**
Jaeger, Lorenz & Köster, Postfach 16 20
D-82121 Gauting b. München (DE)

(54) **Apparatus for endosteal fixation of a substitute ligament by screw insertion.**

(57) An interference screw 16 and a cannulated sheath 1 for fixating ligaments. A graft, attached between previously cut bone blocks, is placed under tension in a graft tunnel 8. The sheath 1 has a cutout 17 at one end such that during screw insertion, the graft is covered by the sheath 1 and protected from the threads of the screw 16, while the bone to which the graft is being fixed is exposed to the threads of the screw 16. The screw 16 is driven between the bone to which the graft is being fixed and a corresponding one of the bone blocks. The screw 16 may be cannulated for insertion over a pre-positioned guide pin.

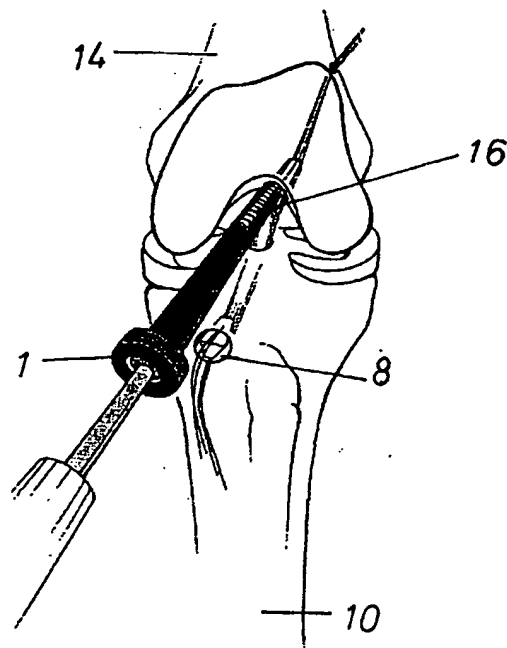


FIG. 2

BACKGROUND OF THE INVENTION

The present invention relates to a device for endosteal fixation of a ligament by screw insertion and, more specifically, to an interference screw and cannulated sheath.

When a ligament or tendon becomes detached from a bone, surgery is usually required to resecure the ligament or tendon. Often, a substitute ligament or graft is attached to the bone to facilitate regrowth and permanent attachment. Various methods of graft attachment are known, such as staples and sutures over buttons. However, such methods often do not provide a sufficiently strong attachment to withstand the normal tensile loads to which they are subjected.

A stronger graft attachment is obtained by using an interference screw to wedge a graft bone block to the wall of a graft tunnel formed through the bone. Fig. 1 illustrates this method, in which the graft 2, with bone blocks 4, 6 at each end, is pulled through a graft tunnel e in the tibia 10, by applying a tensile force on sutures 12 attached to leading bone block 6. The leading bone block 6 is brought forward into the femur 14 until it is fully nested in a graft tunnel in the femur. Then, with tension applied to the graft 2 via sutures 12, a driver is used to insert interference screws 16 between the bone blocks 4, 6 and the graft tunnel, first in the femur and then in the tibia. Although interference screw attachment by the above-described method is more secure than using staples or the like, the graft can be inadvertently cut or frayed by the sharp edges of the interference screw during insertion and after fixation.

Accordingly, it is an object of the present invention to provide an apparatus for screw fixation of ligament grafts which minimizes the likelihood of damage to the graft during and after fixation.

The present invention achieves the foregoing objective by providing a cylindrical cannulated sheath for protecting the ligament graft during insertion of an interference screw. The sheath is configured such that one end includes a cutout portion extending preferably around up to one-half the circumference of the sheath, preferably one-third. The cutout enables the interference screw to be exposed to the tunnel wall of the bone during insertion, while at the same time covering the side of the screw facing the graft, thus protecting the graft from the screw threads during screw insertion. The sheath may optionally be provided with a thread-like continuous ridge on its outer surface to facilitate rotational insertion and removal of the sheath.

In one embodiment of the invention, a guide pin is used to guide the sheath. In this case, the interference screw is also cannulated and guided by the guide pin to the proper position between the graft bone block and the bone.

The screw is preferably configured with a rounded back end (i.e. no threads are provided on the end of the screw) to prevent inadvertent cutting or fraying of the graft by the screw after the screw has been inserted. The leading end of the screw is preferably tapered while the back end has preferably an inverse hex-head for receiving a hex-head screwdriver. A cannulated hex-head screwdriver is used in the guide pin embodiment.

The interference screw is preferably made of titanium, although, other hard metals may be used, such as titanium alloys, stainless steel and stainless steel alloys, and certain biodegradable materials specially tailored for hardness, tensile strength, and compressive strength. The sheath is preferably made of a plastic material or other soft material capable of adequately holding the screw.

When using the apparatus of the present invention the following steps are performed:

Drilling a graft tunnel through adjacent bone masses,
extending a substitute ligament with bone blocks in the graft tunnel under tension between the adjacent bone masses,
inserting the cannulated sheath of the present invention into the ligament tunnel at a rotational position such that the graft is covered and protected by the sheath and the bone tunnel wall is exposed by the cutout at the leading end of the sheath,
inserting an interference screw into the cannula of the sheath,
driving the interference screw between the tunnel wall exposed by the cutout and the bone block portion of the graft, and removing the sheath.

In another embodiment of the present invention, a guide pin is inserted in the graft tunnel before positioning the cannulated sheath. The interference screw is cannulated and is guided by the guide pin during insertion and driving of the interference screw.

In yet another embodiment, the interference screw is inserted into the cannula of the sheath before positioning the sheath, and the screw and the sheath are positioned simultaneously.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

Figure 1 shows a typical graft attached between two previously cut bone blocks being positioned in a graft tunnel.

Figure 2 shows the cannulated sheath of the present invention being used to insert an interference screw

- driven between the bone mass and the corresponding bone block.
- Figure 3 shows the cannulated sheath of the present invention with the interference screw which is exposed by the cutout and is cannulated, so that a guide pin can be inserted.
- Figure 4 shows a side view of the cannulated sheath of the present invention with the interference screw to be placed in the cutout.
- Figure 5 shows a side view of the interference screw of the present invention.
- Figure 6 shows a cannulated interference screw of an alternate embodiment of the present invention.

Referring to Figs. 2, 3 and 4, the present invention is a cylindrical cannulated sheath 1 which receives an interference screw 16 for use during endosteal fixation of a substitute ligament or graft 2.

The sheath 1 has a head 3 at one end and a cutout 17 at the other. The cutout 17, which extends over up to one-half of the circumference (preferably onethird) of the cylindrical sheath 1, enables the interference screw to be driven into the bone mass or tibia 10, while at the same time protecting the graft from inadvertent damage such as fraying or cutting by the screw threads 19. The sheath preferably includes a continuous thread-like ridge 5 on its outer surface, which allows the sheath to be rotated in and out of position. The sheath is preferably made of plastic.

As shown in Fig. 5, the front end of the interference screw 16 is tapered while the back end has rounded edges 21 and includes an inverse hex head 7 adapted to receive a hex head screwdriver. The rounded back edges 21 eliminate inadvertent damage to the graft after fixation.

The interference screw is preferably made of titanium, although, other hard metals may be used, such as titanium alloys, stainless steel alloys, and certain biodegradable materials specially tailored for hardness, tensile strength, and compressive strength.

In an alternate embodiment as shown in Fig. 6, the interference screw 16' is cannulated for receiving a guide pin (20) as shown in Fig 3. The guide pin (20) is positioned between the graft bone block and the femur 14 for guiding the sheath 1 and the cannulated screw 16' into position. A cannulated hex head screw driver is used to drive the cannulated screw.

The use of the apparatus of the invention will now be described in conjunction with Fig. 2, it being understood that endosteal fixation of a substitute ligament or graft is well known in the art. See, e.g. Kurosaka et al. "A Biochemical Comparison of Different Surgical Techniques of Graft Fixation in Anterior Cruciate Ligament Reconstruction," Am. Jour. Sports Med., Vol. 15, No. 3, pp. 225-229, herein incorporated by reference.

As is the usual practice in the art, a graft tunnel 8 is first drilled through the adjoining bones, in this case the tibia 10 and the femur 14. A graft 2, attached between previously cut bone blocks, preferably a patellar tendon, is extended under tension within the graft tunnel 8 between the tibia 10 and the femur 14. In the present invention, a guide pin 20 is then hand positioned between the bone block 6 and the graft tunnel 8 adjacent the femur 14. The cannulated sheath 1 of the invention is placed over the guide pin 20 and guided to a position such that the graft 2 is covered by the sheath 1, while the graft tunnel 8 in the femur 14 is exposed by the cutout 17. The cannulated interference screw 16' is then placed over the guide pin and inserted into the cannula 13 of the sheath 1. The interference screw 16' is driven into the graft tunnel 8 between the femur 14 and the bone block 6. During screw insertion, the sheath 1 covers the graft 2, thus protecting the graft from inadvertent damage that may be caused by the screw threads 19. The cannulated sheath 1 is then removed by rotation with the aid of the thread-like ridge 5, and the guide pin 20 is removed. A similar interference screw is driven into the tibia 10 by the same process to attach the opposite end of the graft.

In an alternate embodiment, the interference screw 16 is inserted in the cannula 13 of the sheath 1 before positioning the sheath 1 between the graft 2 and the femur 14, such that the sheath 1 and the screw 16 are positioned between the graft 2 and the femur 14 simultaneously.

The present invention provides a tight interference fit between the graft bone block 6 and the femur 14 and between the graft bone block 4 and the tibia 10, enabling early mobilization and rapid healing. Still further, the attachment provided by the present invention has superior tensile and compressive strength as well as superior effective stiffness strength as compared to other ligament replacement procedures.

The previous example is for illustrative purposes only, as the present invention is not limited to any type of ligament replacement. Those skilled in the art can certainly contemplate a variety of different procedures in which the present invention can be advantageously applied.

Claims

1. An apparatus for endosteal fixation of a substitute ligament by screw insertion, comprising:
an interference screw (16); and
a cylindrical cannulated sheath (1) which is configured to receive said interference screw (16) and has

first and second ends, said second end including a cutout (17) for exposing a portion of said interference screw (16) during screw insertion for preventing said interference screw (16) from damaging the graft during screw insertion.

- 5 **2.** Apparatus according to claim 1,
 characterized in that
 said first end is configured to receive said interference screw (16) during screw insertion.
- 10 **3.** Apparatus according to claim 1 or 2,
 characterized in that
 said cutout (17) extends over less than one-half, in particular one-third, of the circumference of said sheath (1).
- 15 **4.** Apparatus according to any of the preceeding claims,
 characterized in that
 the outer surface of said sheath (1) has a continuous threadlike ridge (5) to facilitate insertion and removal
 of said sheath (1) into and out of position for screw insertion.
- 20 **5.** Apparatus according to any of the preceeding claims,
 characterized in that
 said cannulated sheath (1) is made of a plastic material and/or that the interference screw (16) is made
 of titanium.
- 25 **6.** Apparatus according to any of the preceeding claims,
 characterized in that
 said interference screw (16) is tapered at one end thereof and has rounded edges at the other end.
- 30 **7.** Apparatus according to any of the preceeding claims,
 characterized in that
 said interference screw (16) has an inverse hex-head for receiving a hex-head screwdriver at one end
 thereof, said end having preferably rounded edges.
- 35 **8.** Apparatus according to any of the preceeding claims,
 characterized in that
 said interference screw (16) has a cannula (13) for receiving a guide pin (20).
- 40 **9.** Interference screw as described in any of claims 1 to 8.
- 45 **10.** Cylindrical cannulated sheath as described in any of claims 1 to 5.
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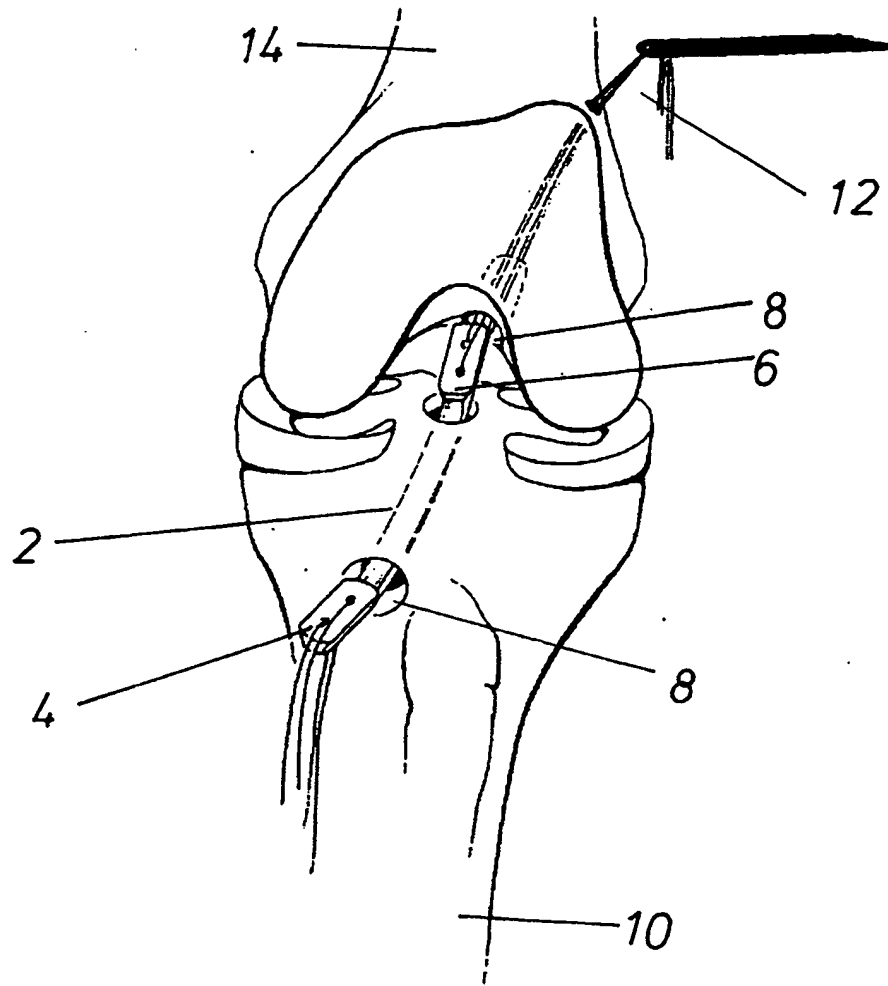


FIG.1
PRIOR ART

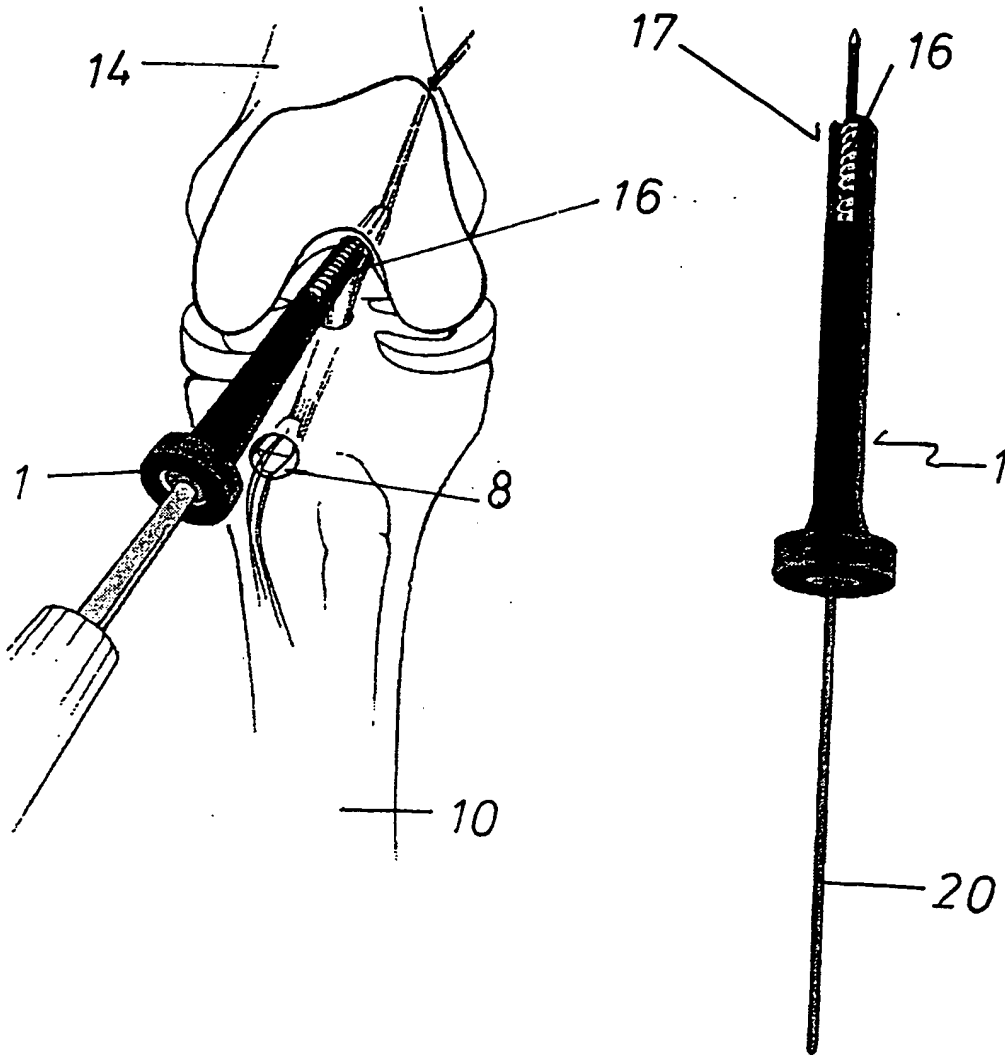


FIG. 2

FIG. 3

FIG. 4

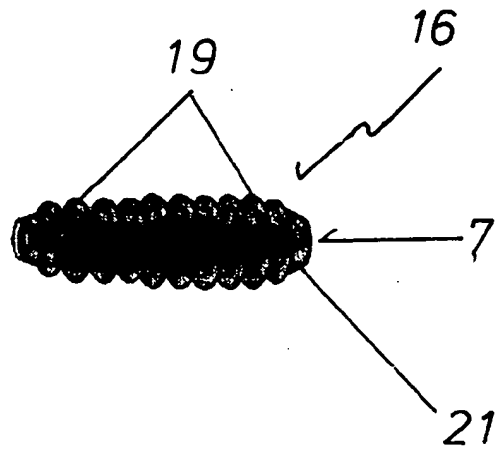
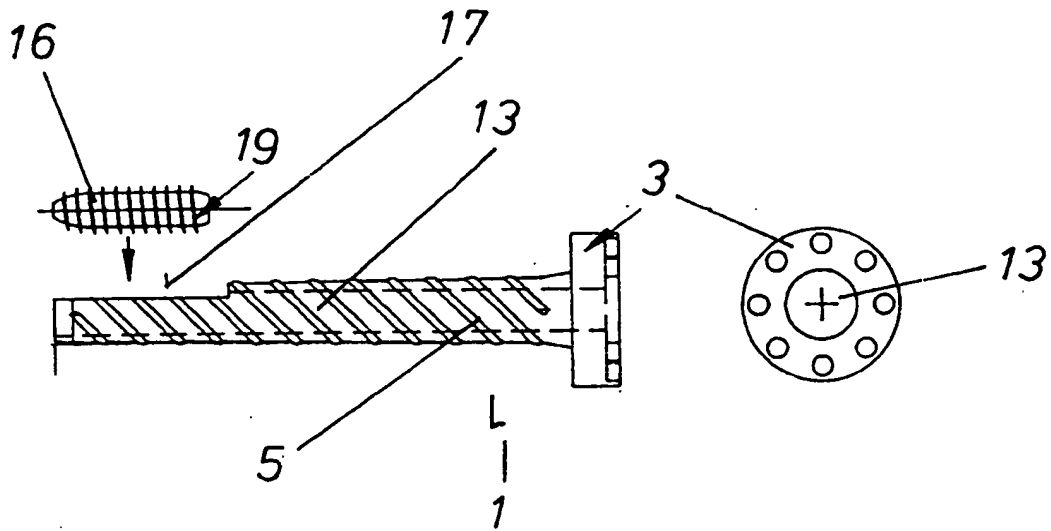


FIG. 5

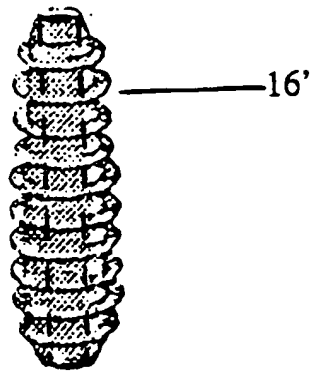


FIGURE 6



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 93100681.1
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 5)
A	<u>US - A - 4 877 020</u> (VICH) * Totality; especially fig. 2 * -----	1, 2	A 61 B 17/56
			TECHNICAL FIELDS SEARCHED (Int. Cl. 5)
			A 61 B A 61 F
The present search report has been drawn up for all claims			
Place of search VIENNA	Date of completion of the search 26-05-1993	Examiner ZAWODSKY	
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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